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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,762	03/19/2001	Virginia Goss Tusher	M-10523 US	8102

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/11/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,762

Applicant(s)

TUSHER ET AL.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, 28-34, 44, 46, 51, 53, 54, 58, 60, and 61; drawn to a method or computer readable storage device or computer system for analyzing a plurality of sets of values associated with a plurality of genes to identify genes with values which differ by a statistically significant amount among the sets, classified in class 702, subclass 19. If this Group is elected then the following two (2) specie elections are also required.
- II. Claims 23-27, 45, 52, and 59; drawn to a method for analyzing a plurality of sets of values associated with genes to identify genes wherein the associated values correlate with patient survival time, classified in class 702, subclass 19.
- III. Claims 35-38, 48, 49, 55, 56, 62, and 63; drawn to a method for reducing statistical error of a set of associated values of genes via processing with a smooth weighting function, classified in class 702, subclass 19.
- IV. Claims 39-43, 50, 57, and 64; drawn to a method for comparing a first and second set of associated values of genes utilizing odd root values, classified in class 702, subclass 19.

FIRST SPECIE ELECTION REQUIREMENT FOR GROUP I:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: identification practice of genes via statistical significance without requiring additionally the identification of falsely identified values as generically described in claim 1, for example.

Specie B: identification practice of genes via statistical significance with requiring the identification of falsely identified values as in claim 32, for example

The above species are distinct and would require an undue search burden if searched together because the identification of false values in a data set requires a clearly additional analysis for such identification which is not apparent in data as it is generally collected and analyzed in the published literature. False positives and false negatives, for example, have been described for various assays, especially for medical purposes, but is a completely separate set of analyses from the simple evaluation of whether a value which has been observed or calculated falls or does not fall in a normal versus statistically significant range of values because false data values requires a determination of errors of measurement, artifact evaluation in experimentation, etc. which is not commonly published with basic statistical analysis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-22, 28-31, 33, 44, 46, 51, 53, 58, and 60 are generic to above listed species A and B in Group I.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

SECOND SPECIE ELECTION REQUIREMENT FOR GROUP I:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie C: identification practice of genes wherein there is no required transmitting of a program of instructions to a client, e.g. generically in instant claim 1

Specie D: identification practice of genes wherein there is a required transmitting of a program of instructions to a client, e.g., as in instant claim 54

The most commonly performed and published methodology in scientific analysis such as gene value analysis is the method per se without publishing what may or may

not be performed for the transmitting of such methodology or information or instructions therefor. The dissemination of methodology, information, or instructions is a distinct function which is generally performed for collaboration purposes or for client business purposes which are actions separately decided upon and performed for each analysis type thus documenting the undue search burden if the above two species are searched together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-22, 28-34, 44, 46, 47, 58, 60, and 61 are generic to the above species C and D in Group I.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons: The inventions of Groups I - IV are unrelated regarding the central inventive limitations therein. The inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, function, and effects in that the Groups are directed to distinct analysis types as summarized with respect to each of the Groups I – IV as summarized above and as follows. Group I is directed to a method or computer readable storage device or computer system for analyzing a plurality of sets of values associated with a plurality of genes to identify genes with values which differ by a statistically significant amount among the sets. Group II is directed to a method for analyzing a plurality of sets of values associated with genes to identify genes wherein the associated values correlate with patient survival time. Group III is directed to a method for reducing statistical error of a set of associated values of genes via processing with a smooth weighting function. Group IV is directed to a method for comparing a first and second set of associated values of genes utilizing odd root values,

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

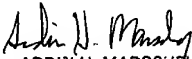
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 10, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER